

**REMARKS**

Applicants have carefully considered the Office Action of November 14, 2007. Claims 11-24 are currently pending. Claims 11, 13 and 21 have been amended to refine and more clearly define that which Applicants consider to be their invention. Newly added dependent claim 24 is directed to a coating having a thickness in the range of about 10  $\mu\text{m}$  to about 200  $\mu\text{m}$ .

Accompanying this Amendment is the Declaration of Dr. Fleming Madsen, a named inventor, an expert in chemical engineering, and a former Professor at The Danish University of Pharmaceutical Sciences. Dr. Madsen's curriculum vitae and two supplemental references are also attached.

Applicants have also amended the specification to correct spelling errors and replace the term "natriumperoxydisuphate" with "sodium peroxydisulphate", and corrected other minor grammatical errors in Examples 1-6 and 12 of Applicants' specification. No new matter has been added by Applicants' amendments.

**Rejections under 35 U.S.C. §112**

Claims 11-23 were rejected under 35 U.S.C. §112, second

paragraph, as being indefinite because the Examiner stated that it was unclear whether the phrase "photoinitiator having a water soluble peroxydisulphate" referred to the disulphate itself, or in combination with another photoinitiator. Applicants have amended claims 11 and 21 to recite "a water soluble peroxydisulphate photoinitiator" to clarify Applicants' invention. Applicants request withdrawal of this rejection.

Claims 15 and 16 were also rejected under 35 U.S.C. §112, second paragraph, as being indefinite because the Examiner alleges that the term "and copolymers or blends of the foregoing" is not clear. Applicants respectfully traverse this rejection.

The language of claim 15 comes directly from Applicants' specification at page 16, lines 19-24. The specification identifies a number of hydrophilic saturated polymer species useful in creating a hydrogel. These polymer species could also include copolymers comprising one or more of the species identified in the specification (or claim). For example, Applicants' Example 1 describes a copolymer of polyethylene glycol dimethacrylate, which is then mixed with polyvinylpyrrolidone. In Applicants' Example 4, a copolymer of vinylpyrrolidone and vinylacetate is described (See, Declaration of Dr. Madsen at ¶¶7-8). As such, Applicants submit that the language of claims 15 and 16 is sufficiently definite for

one of ordinary skill to understand the metes and bounds of the claims' intended scope, and therefore, Applicants respectfully request withdrawal of this rejection.

Rejections under 35 U.S.C. §103(a)

The Examiner again rejected claims 11-23 as obvious over USP Application 2001/0044482 to Hu et al., in view of USP 5,844,016 to Sawhney et al. The Examiner asserts that Hu et al. disclose all of the elements of the claimed composition, except for the use of a water soluble peroxydisulphate photoinitiator, which is disclosed by Sawhney et al. Therefore, according to the Examiner, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to combine the compositions of Hu et al. and Sawhney et al. to arrive at Applicants' claimed invention. Applicants respectfully traverse this rejection.

A. The Combination of Hu Et Al. and Sawhney et al. Does Not Teach All the Elements of Applicants' Amended Claims

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As the Examiner admits, Hu et al. fail to teach any peroxydisulphate photoinitiators in the water-soluble polymer hydrogels. Sawhney et al. teach hydrogel polymers as tissue glues

used in surgical applications. There is only one example in Sawhney et al. where 0.02 g of peroxydisulphate is used, and it is at a higher concentration (2% by weight) than claimed by Applicants. Furthermore, Sawhney et al. also teach that the peroxydisulphate initiator gel does not adhere to tissue as well as the eosin initiator gel (Declaration of Madsen at ¶¶10-13).

In contrast, Applicants' specification contains a number of polymerization examples with lower peroxydisulphate concentrations of between about 1% to 1.25% by weight, compared to Sawhney et al. Applicants' Example 12 shows hydrogel polymerization with a ten-fold lower concentration of 0.2% by weight of persulfate. Applicants teach that the concentration of peroxydisulphate in the hydrogel can be 0.1% to 5.0% by weight.

In the attached Declaration of Dr. Madsen, Applicants present additional experimental data. The first experiment confirms that a 5 mm thick gel made using the claimed composition can be cured with 0.2% persulfate in 1.5-2 minutes. The second experiment shows that a 2 cm thick gel can be cured with 1% by weight persulfate in only 4-5 minutes using the claimed composition, thus showing that the lower persulphate concentrations are indeed significant (Declaration of Madsen at ¶¶27-32).

Furthermore, Applicants also point out that all of the hydrogel examples or applications in either Hu et al. (contact lenses) or Sawhney et al. (tissue glue) have thicknesses between 30  $\mu\text{m}$  to 100  $\mu\text{m}$ , which is  $1/50^{\text{th}}$  as thick as the 5 mm (5000  $\mu\text{m}$ ) sheet produced in Applicants' examples (Declaration of Madsen at ¶15).

Moreover, in Sawhney et al., the peroxydisulphate is not taught as a photoinitiator, but as a thermal (redox) initiator, for which it is well known in the art. See, for example, col. 21, line 60 of Sawhney et al., discussing peroxygen compounds in Example 19. Example 19 compares the differences between the times to gelation for hydrogen peroxide and for potassium persulphate. Nowhere in Example 19 is UV photoirradiation of the peroxide containing sample taught or suggested. Every other example in Sawhney et al., that discusses gelation or adhesion, teaches photoirradiation with green light, and specific wattage, and also teaches the use eosin Y or Igracure® as the photoinitiator (Declaration of Madsen at ¶¶12-13).

Hence, the combination of Hu et al. in view of Sawhney et al. does not teach all of the features of Applicants' claimed invention, i.e., the combination does not teach that water soluble hydrophilic polymers can be satisfactorily cured by the use of peroxydisulphate photoinitiators and photoirradiation at the concentration claimed by Applicants.

B. The Examiner's Addition of Applicants' Statements in the Background Section of Applicants' Specification Does Not Support the Obviousness Rejection Over the Combination of Hu et al. In View of Sawhney et al.

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In order to cure the above deficiency, i.e., that the combination of Hu et al. in view of Sawhney et al. does not teach that water soluble hydrophilic polymers can be satisfactorily cured by the use of peroxydisulphate photoinitiators and photoirradiation, the Examiner points to Applicants' statements in the Background section of the present application, which teach that peroxides in general were known in the art as photoinitiators of vinyl polymerization. The Examiner then combines Applicants' statement with the teachings of Hu et al. and Sawhney et al., and argues that one of ordinary skill in the art, at the time the invention was made, would have been motivated to combine Hu et al. in view of Sawhney et al. and in view of the prior art knowledge of photoinitiators, as discussed by Applicants, to arrive at Applicants' invention with a reasonable expectation of success.

The Examiner's argument supporting the combination of Hu et al. in view of Sawhney et al., and also in view of Applicants' prior art statements, cannot stand because Applicants' statements

were summarizing the prior art use of peroxides and persulphates on non-water soluble, unsaturated vinyl monomers and polymers, not the novel use of persulphates with hydrophilic unsaturated polymers as taught by Applicants' claimed invention (Declaration of Madsen at ¶19). As such, the combination of Hu et al. in view of Sawhney et al. and Applicant's Background statements still does not teach all of the features of Applicants' claimed invention, i.e., the combination does not teach that water-soluble hydrophilic polymers can be satisfactorily cured by the use of peroxydisulphate photoinitiators and photoirradiation at the concentration claimed by Applicants.

To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicants submit that in view of the amended claims, the Examiner has failed to establish a *prima facie* case of obviousness with regard to Applicants' claimed invention, because the combination of references does not teach all of Applicants' claimed features.

C. One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine the Teachings of Hu et al. in view of Sawhney et al. to Arrive at Applicants' Claimed Invention.

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Applicants also submit that one of ordinary skill, at the time the invention was made, would not have been motivated to combine the teachings of Hu et al. and Sawhney et al., to arrive at Applicants' claimed invention, with any reasonable expectation of success.

The problem to be solved by Applicants was to find a way to lessen the time it took to prepare and completely cure cross-linked water-soluble hydrogel sheets or coatings, up to 2 cm thick, in a simple and non-toxic manner (Declaration of Madsen at ¶14).

As the Examiner admits, Hu et al. teach polyvinylpyrrolidone as an example of saturated hydrophilic polymers for contact lenses; however, Hu et al. do not teach the use of peroxydisulphates as photoinitiators, but teach the use of benzophenones. Sawhney et al. teach a surgical sealant or glue. Sawhney et al. is offered by the Examiner for teaching the use of eosin and peroxides as photoinitiators in surgical adhesives but also mentions peroxydisulphate. Both lenses and sealants generally



have a thickness between about 30  $\mu\text{m}$  to 100  $\mu\text{m}$ . Polymerization times in such thin sheets are not usually a significant problem. As such, Applicants submit that one of ordinary skill in the art would not have been motivated to consider Hu et al. when attempting to solve Applicants' problem because the hydrogels of Hu et al. are thin (Declaration of Madsen at ¶15).

Moreover, one of ordinary skill, when reading Sawhney et al., would not have found any teaching or suggestion to use peroxydisulphate compounds to photoinitiate the curing of the hydrogels, because Sawhney et al. only teach the use eosin Y or Igracure as photoinitiators. As such, those of ordinary skill in the hydrogel art would not have had any motivation to try to use peroxydisulphate compounds taught in Sawhney et al. to photoinitiate the curing of water-soluble polymer hydrogels, and would not have had any reasonable expectation of success to do so (Declaration of Madsen at ¶17).

With regard to the Examiner's mention of Applicants' Background discussion on prior art vinyl polymerization, Applicants submit that the statements merely summarize the prior art use of peroxides and persulphates as photoinitiators and thermal initiators on non-water soluble, unsaturated vinyl monomers and polymers. Until the present application, these photoinitiators had

never been used on hydrophilic water-soluble polymers. In other words, one of ordinary skill would have understood from Applicants' Background statements that the prior art taught away from the claimed combination (Declaration of Madsen at ¶19).

Further support for Applicants' position regarding the prior art can be found in the Declaration of Madsen discussing two recent articles in the same technological area by Ikkai and Adachi. These references date from 2004 and 2007, and state that their papers contain the first reported UV-induced gelation method using persulfate as a photoinitiator. The authors are apparently unaware of Applicants' published patent application (with a priority date of 2002), but the essence is that their work in both references supports both Applicants claims and the suggested mechanism (Declaration of Madsen at ¶¶20-23).

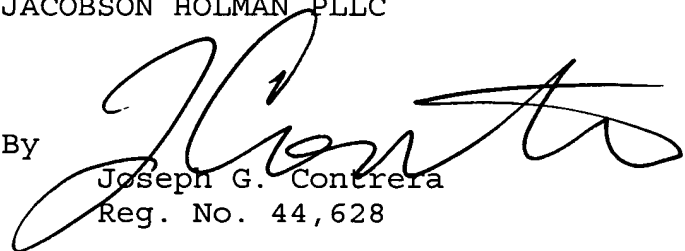
Therefore, Applicants submit that one of ordinary skill in the art, at the time the invention was made, would not have been motivated to combine the teachings of Hu et al. and Sawhney et al. with what was known in the prior art, to arrive at Applicants' claimed invention, with any reasonable expectation of success. Applicants respectfully request withdrawal of this rejection.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all currently outstanding rejections, and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By



Joseph G. Contrera  
Reg. No. 44,628

400 Seventh Street, N.W.  
Washington, D.C. 20004-2201  
(202) 638-6666  
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HBJ/JGC/

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